DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 758-7115
FAX: (612) 334-4142

January 19, 2005

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 05 - 08

Joseph M. Hogan
President and Chief Executive Officer
GE Healthcare Technologies
3000 N. Grandview Boulevard
Waukesha, Wisconsin 53118

Re: Field Test Number GI-72694

Dear Mr. Hogan:

On December 20, 2004, an inspector from the State of New Mexico (under contract with the Food and Drug Administration (FDA) conducted a field test of the certified diagnostic x-ray system at the following facility:

[redacted]

X-Ray Control Manufacturer: GE
X-Ray Control Model/ Serial No.: 2289299-2 / BRDE42
Room No.: 2

Our records indicate that your firm assembled this system (FDA-2579; G144980) on 12/26/2003, and we tested this system to determine its compliance with portions of the Performance Standard for Diagnostic X-Ray Equipment (21 C.F.R. §§ 1020.30-32). Diagnostic x-ray equipment are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This letter confirms our telephone notification on 1/13/2005 to Ms. Lori Barikmo, HHS Process Leader, of your firm. During this telephone call we

requested that you immediately correct the following serious non-compliance with the performance standard:

- During testing on December 20, 2004, x-ray production was possible when the primary protective barrier was not in position to intercept the x-ray beam as required by 21 C.F.R. § 1020.32(a).

We request that you, as the responsible assembler, investigate the deviation from the performance standard and/or the defect listed above in accordance with 21 C.F.R. §§ 1003 and 1004, as follows:

If you determine that the deviation and/or defect is caused by improper assembly or installation, you should correct the deviation and/or defect at no charge to the user by either repairing the system, replacing it, or refunding the cost.

If you determine that the deviation and/or defect is caused by the factory-based manufacturer, you should notify the manufacturer of the deviation and/or defect and send documentation of such notification to this office.

If you can establish that the system is compliant, that the alleged deviation and/or defect does not exist or does not relate to the safety of the product, or is directly attributable to user abuse or lack of maintenance, you may submit such evidence to this office in accordance with 21 C.F.R. § 1003.11(a)(3) within fifteen (15) working days of receipt of this letter.

You are requested to report the results of your investigation and follow-up action to this office within fifteen (15) working days of the receipt of this letter. Your response should include the date that the corrective actions were completed, and a copy of the service record and/or other supportive documents.

Failure to respond constitutes a violation of the Act, Sections 538(a)(2) and 538(a)(4) of Sub-chapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968). Failure to promptly correct this violation can result in regulatory action being initiated by FDA without further notice. These actions include seizure, injunction, and the imposition of civil penalties as provided for in Section 539 of the Act. Persons violating Section 538 of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum of $300,000.

Your response should be sent to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 N. Mayfair Road, Suite 200,

Milwaukee, WI 53226-1305. If you have any questions, please contact Mr. Garvin at (414)771-7167 x 12.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

TWG/ccl

xc: [redacted]

Larry Kroger, Ph.D.
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